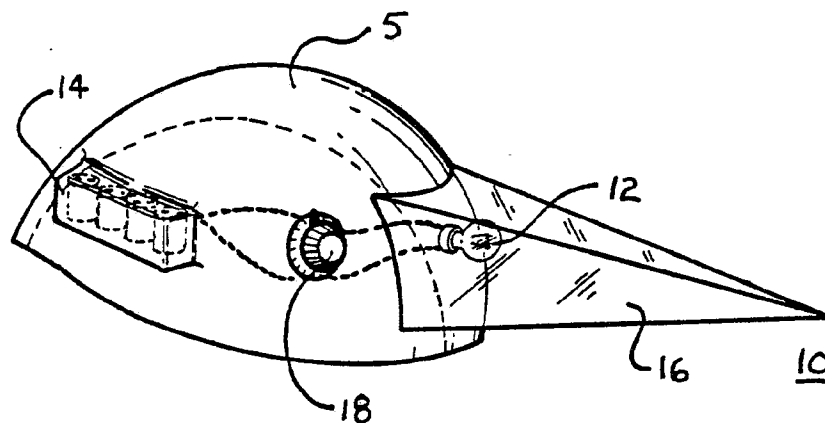


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(21) International Application Number: PCT/US89/00934 (22) International Filing Date: 8 March 1989 (08.03.89) (31) Priority Application Number: 165,285 (32) Priority Date: 8 March 1988 (08.03.88) (33) Priority Country: US (71)(72) Applicant and Inventor: BRAINARD, George, C. [US/US]; 813 Mt. Vernon Avenue, Haddonfield, NJ 08033 (US). (74) Agent: JOHNSON, Philip, S.; Woodcock Washburn Kurtz Mackiewicz & Norris, One Liberty Place, 46th Floor, Philadelphia, PA 19103 (US).		(81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent). Published <i>With international search report.</i>

(54) Title: PORTABLE LIGHT UNIT FOR STIMULATING NEUROENDOCRINE SYSTEM

**(57) Abstract**

Light weight phototherapeutic devices are provided that emit an illuminance of at least 200 lux on the eyes of a wearer. The device is portable and can be used in the phototherapy of depressed patients, shift-workers and those affected by jet-lag and seasonal affective disorders.

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PORTABLE LIGHT UNIT FOR STIMULATING NEUROENDOCRINE SYSTEMFIELD OF THE INVENTION

5 This invention relates to apparatus and treatments for phototherapy and in particular to more convenient treatments for affecting the neuroendocrine system, circadian rhythms and circannual rhythms in humans..

BACKGROUND OF THE INVENTIONS

10 The biological effects of light are increasingly being recognized as playing an important role in modern healthcare. Phototherapy, the use of light as a treatment, has been successfully used to treat a number of diseases including psoriasis and rickets. More recently, scientists
15 have discovered that sunlight plays a critical role in the regulation of circadian and circannual rhythms in humans. Accordingly, increased attention is being paid to the use of phototherapy in diseases influenced by daily and seasonal rhythms. Phototherapy has been demonstrated to
20 have significant effects in the treatments of several diseases of particular interest to psychiatrists, including affective illness and chronobiological disorders. It has also been used with some success in the treatment of psychiatric disorders which have a "seasonal component",
25 for example, seasonal affective disorder "S.A.D".

Light has been shown to have a number of psychological effects on the human central nervous system which may be separate from its visual effects. Very bright light, i.e. above about 2000 lux, is capable of suppressing

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the production and release of the pineal hormone and can set the internal "clock", within a certain range, for circadian rhythms. Reference is herein made to F.M. Jacobsen et al., "Seasonal Affective Disorder and the Use of Light as an Antidepressant", Directions in Psychiatry, Vol 6, 1986, which is herein incorporated by reference.

One currently prescribed treatment for phototherapy is to have patients sit approximately three feet from a light box which typically has dimensions of about 2' by 4'. These light boxes are generally awkward and cumbersome to use. Furthermore, the patients are required to sit in one spot for approximately one to five hours, depending on their specific therapy. This has been found to be restrictive and limiting. Additionally, these devices are difficult to transport due to their size and weight and generally require an external power source.

Accordingly, a need exists for a mobile phototherapy treatment which would not require patient inactivity. In addition, a need exists for a phototherapeutic device which is lightweight and self-contained.

SUMMARY OF THE INVENTION

In accordance with the teachings of this invention, an improved phototherapeutic device and phototherapy method are provided. The invention is designed to stimulate the neuroendocrine and circadian systems circannual of the patient with a very bright light of at least 200 lux. This light is portably mounted to a portion of the patient's body, preferably the head, and is directed towards the patient's eyes. The light preferably uses a full white light spectrum and is supplied with power by a battery which is preferably rechargeable. The invention also may chose to deflect heat generated from the light away from the person wearing the unit. It is envisioned that the light can be equipped with a dimmer switch or rheostat so that the user may reduce the intensity of the bulbs. In addition, the device can be

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equipped with filters, such as dichroic filters, neutral density filters and those filters designed to block or screen designated radiation, such as infrared or ultraviolet light. Such filters can be interposed between
5 the lamp of the light and the user's eyes.

Accordingly, a phototherapeutic device and method are provided which permit uninterrupted patient activity during treatment. The device can be used for the treatment of depression, such as SAD, or used by healthy people
10 involved in shift work to overcome resistance by their internal clocks.

Shift work challenges the normal biological rhythms of human beings. People who change work shifts often report psychological discomfort and negative health
15 consequences. Accidents and health related absenteeism are often higher among shift-workers due to the stress in changing schedules. The use of the phototherapeutic device of this invention may prove beneficial in resetting the person's biological clock when he or she changes shifts.
20 Currently, an estimated 20-25% of the work force in the United States is involved in some form of shift work.

Finally, the phototherapeutic device of this invention may be useful for people who travel by plane over multiple time zones. Such travelers experience a malady
25 known as "jet-lag" which can debilitate the traveler for one to four days after the flight. As with shift workers, the device of this invention might be used for a more rapid, effective resetting of the internal biological clock, allowing prevention or quicker recovery from jet
30 lag.

It is, therefore, an object of this invention to provide a portable, head-mounted phototherapeutic device for the treatment of psychiatric disorders.

It is another object of this invention to provide
35 a self-containing phototherapeutic device for delivering bright light to the users eye's for stimulating the circadian and neuroendocrine system of the user.

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It is still another object of this invention to provide an improved method of phototherapy for treating both psychiatric disorders and negative health consequences associated with shift work or jet lag.

5 With these and other objects in view, this invention resides in the novel construction, combination, arrangement of parts and methods substantially as hereinafter described and more particularly defined by the attached claims.

10 BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings illustrate a complete embodiment of the invention according to the best mode so far devised for the practical application of the principles thereof and in which:

15 FIG. 1 : is a perspective illustration of a preferred portable phototherapeutic device of this invention, equipped with a side-mounted battery pack, dimmer switch, light source and heat deflector;

20 FIG. 2 : is perspective illustration of another preferred, portable, phototherapeutic embodiment having a top-mounted battery pack and front-mounted light source;

 FIG. 3 : is a perspective view of another photo- therapeutic embodiment of this invention including a front mounted light source and filter; and

25 FIG. 4 : is a transverse view of another phototherapeutic embodiment of this invention which includes a front mounted light source and remote battery pack for providing a lighter weight construction.

DETAILED DESCRIPTION OF THE INVENTION

30 Referring now to the figures and particularly to FIG. 1, there is shown a portable phototherapeutic device 10 having a heat deflector 16 and head mounting device 5. The device 10 is provided with a light source 12 and battery pack 14. It becomes readily apparent that this
35 device 10 overcomes the problems of excessive size and weight and limited mobility by being light weight, self-contained and head-mounted. The device 10 can also be

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fitted with a rheostat 18 for permitting a patient to adjust the intensity of the light source 12.

An alternative embodiment is illustrated in FIG. 2 which describes a phototherapeutic device 20 having a light source mounted on an extension of the head mounting means 5. In this fashion, the light source 22 can be more appropriately focused on the eyes of the user. The battery pack 24 of this embodiment 20 is located along the top portion of the head mounting means 5.

10 In FIG. 3, a phototherapeutic device 30 having a radiation shield 36 is described. The light source 32, of this embodiment is attached to the head mounting means 5. Disposed between the eyes of the user and the light source 32 is a filter designed to block or screen designated
15 radiation, such as infrared or ultraviolet light. The filter 36 could also be a dichroic or neutral density filter.

Referring now to FIG. 4, a light-weight phototherapeutic device 40 is illustrated having a remote
20 battery back 44. The light source 42 is disposed on a mounting means 48, which can generally assume the shape of a sun visor. The device 40 is equipped with a member 46 which can correspond to a radiation filter and/or a heat deflection shield. In accordance with this particular
25 embodiment, a strap 48 can be provided for adjustment to various head sizes.

The light sources 12, 22, 32 or 42 preferably comprises an incandescent lamp, preferably a quartz halogen lamp. The intensity of the illuminance produced by these
30 lamps 12, 22, 32, and 42 should be at least 200 lux, although more preferable ranges include from about 200 lux to about 10,000 lux, from about 1000 lux to about 3000 lux, from about 1500 lux to about 2700 lux, and most preferably from about 2000 lux to about 2500 lux. The latter range
35 has been recognized as acceptable. For instance, studies of phototherapy with S.A.D. patients have concluded that bright light (2500 lux) is significantly more effective as

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an antidepressant than the intensity of light ordinarily found in a home or office (100-300 lux). See F.M.

Jacobsen, "Seasonal Affective Disorder and the Use of Light as an Anti-Depressant", Directions in Psychiatry, Vol. 6,

5 1986 which is hereby incorporated by reference.

One acceptable treatment for the symptoms of Seasonal Affective Disorder could be to expose patients to the bright artificial light produced by the phototherapeutic devices of this invention for a period of
10 5 to 6 hours per day. It is understood that the anti-depressant effects could appear within 2 to 6 days after the commencement of treatment, and a relapse often could occur 2-4 days after light treatment is discontinued.

In the treatment of manic-depressive patients, an
15 exposure to 500 lux has been known to cause a 50% suppression of melatonin levels, but produced no effect in the controls. A.J. Lewy, et al, "Manic-depressive Patients May Be Supersensitive to Light", the Lancet, p. 384, February 14, 1981. It has also been demonstrated that when
20 manic-depressants were exposed to a light intensity of 1500 lux, almost complete suppression of melatonin secretion was noted, resulting in levels of approaching those observed during daytime in two healthy subjects. Accordingly, the use of the devices of this invention could be used to
25 suppress human melatonin secretion in manic-depressants and alter the environmental light-cycle which generates their circadian rhythm.

From the foregoing, it has been demonstrated that this invention provides portable, light-weight
30 phototherapeutic devices for stimulating a patient's circadian system and associated neuroendocrine parameters. Although various embodiments have been illustrated, this was for the purpose of describing, but not limiting the invention. Various modifications, which will become
35 apparent to one skilled in the art, are within the scope of this invention described in the attached claims.

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We claim:

1. A phototherapeutic device for treating a patient comprising:

(a) a light source for producing an illuminance
5 of at least 200 lux on the eyes of said patient; and

(b) mounting means for affixing said light source to a portion of the patient's body.

2. The device of claim 1 wherein said mounting means comprises means for attaching said light source to a
10 patient's head.

3. The device of claim 1 wherein said light source comprises means for producing an illuminance of at least about 200 lux to about 10,000 lux.

4. The device of claim 1 wherein said light
15 source comprises means for producing an illuminance of about 1000 lux to about 3000 lux.

5. The device of claim 1 wherein said light source comprises means for producing an illuminance of about 1500 lux to about 2700 lux.

20 6. The device of claim 1 wherein light source comprises means for producing an illuminance of about 2000 lux to about 2500 lux.

7. The device of claim 1 wherein said light source comprises means for producing light having a broad-
25 spectrum white light component.

8. The device of claim 4 wherein said light source comprises means for producing green light.

9. The device of claim 1 wherein said light source comprises means for producing blue-green light.

30 10. The device of claim 7 further comprising heat deflector means for deflecting a portion of the heat from said light source away from the head of said patient.

11. The device of claim 10 wherein said heat deflection means comprises a reflector.

35 12. The device of claim 10 wherein said heat deflection means comprises a dichroic filter.

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13. The device of claim 7 further comprises an ultraviolet filter.

14. The device of claim 7 further comprising a neutral density filter disposed between said light source
5 and said eyes of said patient.

15. A method of phototherapy comprising:

(a) providing a light source having an illuminance of at least about 200 lux,

(b) mounting said light source to the head of a
10 patient; and

(c) illuminating the eyes of said patient with said light source for a time sufficient to stimulate said patient's circadian system.

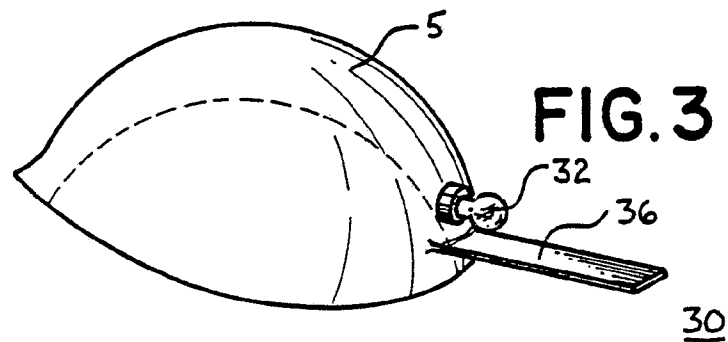
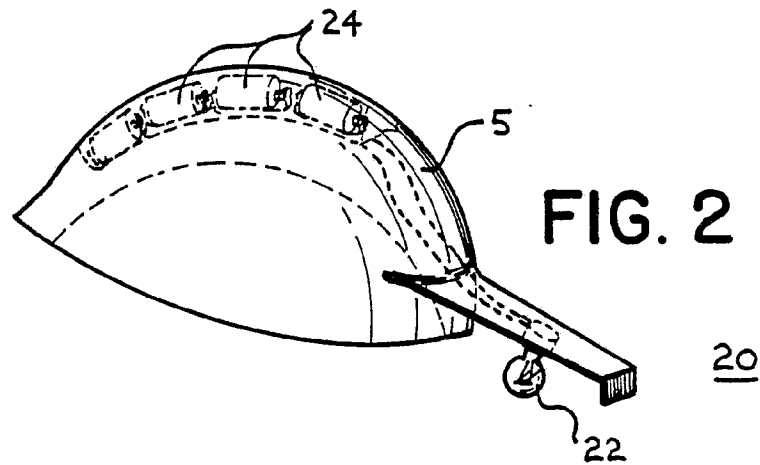
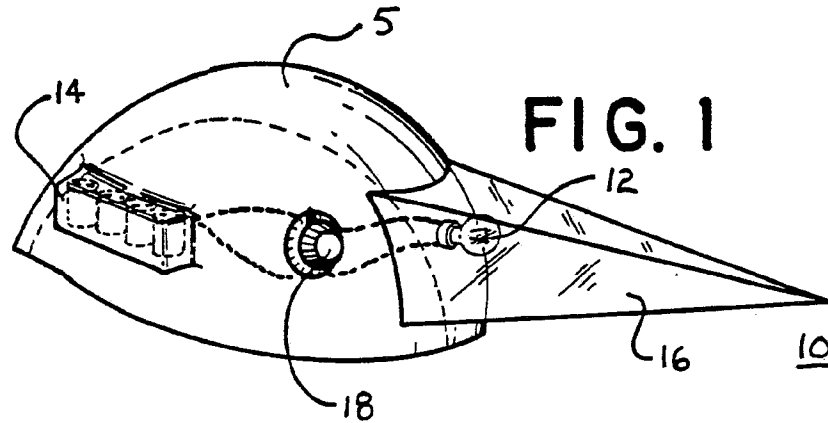
16. The method of claim 15 wherein said
15 illuminating step comprises stimulating the neuroendocrine system of the patient.

17. The method of claim 15 wherein said providing step provides a light source having an illuminance of at least about 1500 lux to about 2700 lux.

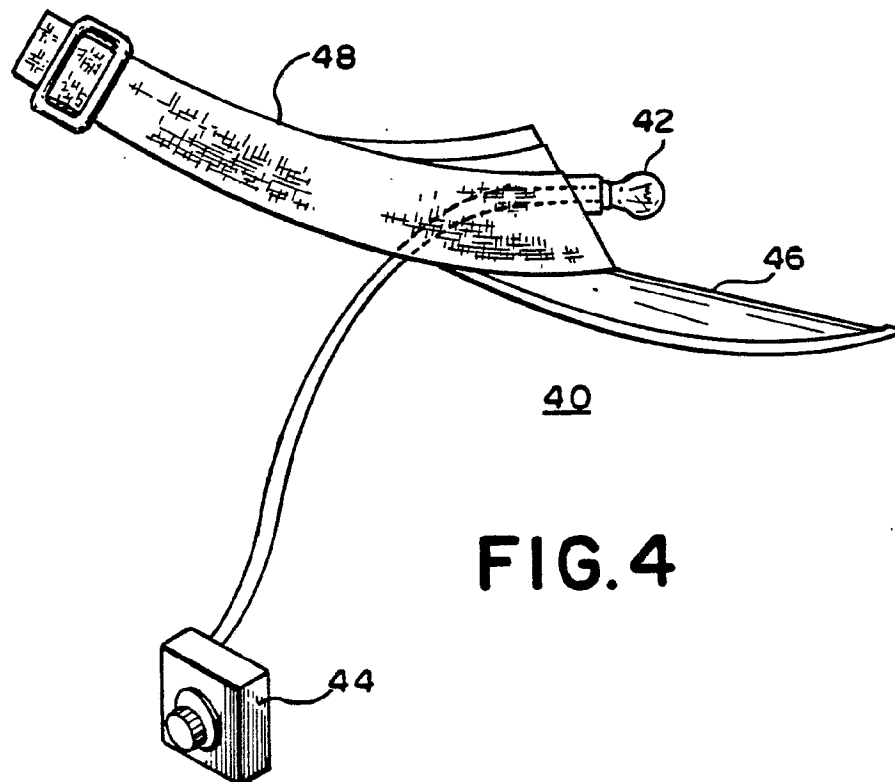
20 18. The method of claim 15 wherein said providing step provides a light source having an illuminance of at least about 2000 to about 2500 lux.

19. The method of claim 18 wherein said providing step provides a light source having a white light
25 spectrum.

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2/2



INTERNATIONAL SEARCH REPORT

PCT/US89/00934

International Application No.

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶ According to International Patent Classification (IPC) or to both National Classification and IPC <div style="text-align: center; margin-top: 10px;"> IPC (4) A61N 5/06 US CL. 128/395 </div>																	
II. FIELDS SEARCHED ⁷ <div style="text-align: center; margin-top: 10px;"> Minimum Documentation Searched </div> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="width: 25%; padding: 5px;">Classification System</td> <td style="padding: 5px;">Classification Symbols</td> </tr> <tr> <td style="text-align: center; padding: 10px;">U.S.</td> <td style="padding: 10px;">128/395, 396, 397, 398, 24.1, 380, 23, 76.5</td> </tr> </table> <div style="text-align: center; margin-top: 10px;"> Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸ </div>			Classification System	Classification Symbols	U.S.	128/395, 396, 397, 398, 24.1, 380, 23, 76.5											
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III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹ <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <th style="width: 10%; padding: 5px;">Category *</th> <th style="width: 70%; padding: 5px;">Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²</th> <th style="width: 20%; padding: 5px;">Relevant to Claim No. ¹³</th> </tr> <tr> <td style="text-align: center; padding: 10px;">Y</td> <td style="padding: 10px;">PHILLIPS, "Let the Sun Shine", 1985. <u>The Chicago Tribune</u>, 11 December 1985.</td> <td style="text-align: center; padding: 10px;">1-9,15-19</td> </tr> <tr> <td style="text-align: center; padding: 10px;">Y</td> <td style="padding: 10px;">US,A, 4,057,054 (GIANNONE) 20 May 1976. See Fig. 1.</td> <td style="text-align: center; padding: 10px;">1-9,15-19</td> </tr> <tr> <td style="text-align: center; padding: 10px;">Y</td> <td style="padding: 10px;">WIRZ-JUSTICE ET AL,; "Light Treatment of Seasonal Affective Disorder in Switzerland", 1986. Acta psychiatr. Scand. 1986:74:193-204.</td> <td style="text-align: center; padding: 10px;">1-10,13, 15-19</td> </tr> <tr> <td style="text-align: center; padding: 10px;">Y</td> <td style="padding: 10px;">US,A, 4,553,534 (STIEGLER) 19 November 1985. See Figs. 1, 2.</td> <td style="text-align: center; padding: 10px;">1-9,15-19</td> </tr> </table>			Category *	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³	Y	PHILLIPS, "Let the Sun Shine", 1985. <u>The Chicago Tribune</u> , 11 December 1985.	1-9,15-19	Y	US,A, 4,057,054 (GIANNONE) 20 May 1976. See Fig. 1.	1-9,15-19	Y	WIRZ-JUSTICE ET AL,; "Light Treatment of Seasonal Affective Disorder in Switzerland", 1986. Acta psychiatr. Scand. 1986:74:193-204.	1-10,13, 15-19	Y	US,A, 4,553,534 (STIEGLER) 19 November 1985. See Figs. 1, 2.	1-9,15-19
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<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>* Special categories of cited documents: ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>																	
IV. CERTIFICATION <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="width: 50%; padding: 5px;"> Date of the Actual Completion of the International Search <div style="text-align: center; margin-top: 10px;">13 April 1989</div> </td> <td style="width: 50%; padding: 5px;"> Date of Mailing of this International Search Report <div style="text-align: center; margin-top: 10px; font-size: 1.2em;">17 MAY 1989</div> </td> </tr> <tr> <td style="padding: 5px;"> International Searching Authority <div style="text-align: center; margin-top: 10px;">ISA/US</div> </td> <td style="padding: 5px;"> Signature of Authorized Officer <div style="text-align: center; margin-top: 10px;"> Mark S. Graham </div> </td> </tr> </table>			Date of the Actual Completion of the International Search <div style="text-align: center; margin-top: 10px;">13 April 1989</div>	Date of Mailing of this International Search Report <div style="text-align: center; margin-top: 10px; font-size: 1.2em;">17 MAY 1989</div>	International Searching Authority <div style="text-align: center; margin-top: 10px;">ISA/US</div>	Signature of Authorized Officer <div style="text-align: center; margin-top: 10px;"> Mark S. Graham </div>											
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